In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-494V

(not to be published)

ANJANETTE WELCH,	*	Special Master Corcoran
	*	
Petitioner,	*	Filed: July 2, 2019
	*	
v.	*	Influenza vaccine; Guillain-Barré syndrome; dismissal; lack of preponderant evidence; expert opinion on timeframe
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Robert P. Goodwin, Walsh Roberts & Grace, Buffalo, NY, for Petitioner.

Voris E. Johnson, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On April 4, 2018, Anjanette Welch filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] ECF No. 1. Petitioner alleged that the influenza ("flu") vaccine she received on October 18, 2016, caused injuries including Guillain-Barré syndrome ("GBS"). *Id.* at 1. After review of the records and other evidence offered by Petitioner to support her claim (including an opinion by her treater/expert that he *could not* state that the flu vaccine was likely causal of her symptoms), I recommended that this case be resolved without hearing, given concerns I had about its ultimate viability. *See* Scheduling

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with Internet access.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "pf any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–34 (2012) (hereinafter "Vaccine Act" or "the Act"). Individual section references hereafter shall refer to §300aa of the Act.

Order (non-PDF), dated Mar. 11, 2019. The parties agreed to this proposition, and Petitioner filed a brief in support of her claim on April 12, 2019. *See* Pet'r's Mot. for a Ruling on the Record (ECF No. 17) ("Mot."). Respondent soon thereafter filed a brief arguing for dismissal of Petitioner's claim. *See* Resp't's Response to Pet'r's Mot. for a Ruling on the Record, filed Apr. 24, 2019 (ECF No. 18) ("Opp."). Petitioner filed a Reply on May 1, 2019. ECF No. 19.

Having completed my review of the evidentiary record and the parties' filings, I hereby **DISMISS** Petitioner's claim, for the reasons stated below.

I. Factual Background

Prior to the vaccination at issue, Ms. Welch's medical history was significant for type 2 diabetes mellitus, hypertension, obesity, arteriosclerosis, pancreatitis, and frequent urinary tract infections ("UTI"). Ex. 2 at 2, 5, 8, 11, filed Apr. 9, 2018 (ECF No. 6-2); Ex. 3 at 11, 13, filed Apr. 9, 2018 (ECF No. 6-3). Her most recent UTI before vaccination was diagnosed on October 3, 2017. Ex. 3 at 13. She did not experience any noted neurological or muscular symptoms in the months prior to the vaccination at issue. *See generally* Ex. 2; Ex. 3.

Petitioner, then age fifty-two, received the quadrivalent flu vaccine at an appointment with The Endocrine Group on October 18, 2016. Ex. 2 at 14. Just over four months later, on February 21, 2017, she visited her primary care physician, Regina Velarde, M.D., reporting symptoms of weakness, poor balance, tingling in her hands and feet, and pain when touching objects. Ex. 4 at 3, filed Apr. 9, 2018 (ECF No. 6-4). She stated that these symptoms had begun a few months earlier and had worsened progressively. *Id.* Petitioner also expressed her view that she had a neuropathy. *Id.* She followed up one week later, still reporting neuropathy-like symptoms at that time. *Id.* at 6–7.

Upon referral, Petitioner visited neurologist Fredric Schoen, M.D., on March 9, 2017. Ex. 5 at 1, filed Apr. 9, 2018 (ECF No. 6-5). At this visit, Ms. Welch recounted that she had first experienced symptoms in December 2016 (more than six weeks post-vaccination), beginning with pain and tingling in her feet, as well as poor balance, and eventually including fatigue, numbness and pain sensitivity in her hands and feet, and facial numbness. *Id.* On examination, Petitioner's reflexes were absent, and she demonstrated some difficulty walking. *Id.* at 3. Dr. Schoen assessed her with a balance problem and a skin sensation disturbance, while noting that her condition could be "a post infection neuropathy or neuropathy related to diabetes." *Id.*

At Dr. Schoen's direction, Petitioner underwent electrodiagnostic testing on March 23, 2017. Ex. 5 at 5–6. This testing showed "no definitive evidence of generalized neuropathy," though it did suggest she had carpal tunnel syndrome. *Id.* at 5. Dr. Schoen again theorized that her condition might be a post-infectious neuropathy, though he also recorded that Petitioner "did have a flu shot last fall but does not remember when." *Id.* at 5–6.

Petitioner underwent a lumbar puncture on April 3, 2017, followed by a brain magnetic resonance imaging ("MRI") on April 14th. Ex. 7 at 8, filed Apr. 9, 2018 (ECF No. 6-7); Ex. 5 at 8–9. At a visit with Dr. Schoen on April 27th, her symptoms were noted to be improving slightly. Ex. 5 at 10. Dr. Schoen recorded that Petitioner "did have a flu shot 2 weeks before onset of symptoms" at this visit. *Id.* He wrote that her condition "may have been postinfectious but I could not guarantee her that," and theorized that her condition also could be small fiber neuropathy. *Id.* at 12.

On July 31, 2017, Petitioner saw rheumatologist Neal Greenstein, M.D., at Dr. Schoen's referral for "further evaluation of possible underlying connective tissue disease." Ex. 9 at 1, filed Feb. 28, 2019 (ECF No. 15-1). She was noted to be positive for antinuclear antibodies ("ANA"), but Dr. Greenstein did not otherwise provide a definitive diagnosis. He opined that her positive ANA "can certainly be related to whatever the event was that occurred back in December and might have been a mild case of Guillain-Barré or possibly a virus." *Id.* at 4.

Petitioner next saw Dr. Schoen on August 7, 2017, at which time he recorded that she "likely had postvaccination neuropathy i.e. very mild Guillain-Barré syndrome." Ex. 5 at 15. Noting that her flu vaccination had occurred on October 18, 2016, he wrote that her numbness began "probably 4 weeks later." *Id.* at 13. On examination, Petitioner's reflexes had returned in her knees and ankles, but remained absent in her arms. *Id.* at 15. Nine days later, at a visit with Dr. Velarde for back pain, Petitioner reported that she had been diagnosed with GBS. Ex. 4 at 8. Petitioner has filed no subsequent medical records.

II. Witness Statement

Petitioner filed a four-page affidavit, in which she recounted her overall course and the severity of her symptoms. *See generally* Ex. 1, filed Apr. 9, 2018 (ECF No. 6-1) ("Pet. Aff."). Ms. Welch stated that she received the flu shot on October 18, 2016, and averred that "[i]n the days following the vaccination, I began to experience a tingling sensation in my hands and feet. I also felt weak and off balance. These symptoms intensified each passing week." *Id.* at 1. She equivocated somewhat about when she first experienced symptoms, however, stating also that her symptoms worsened "[b]etween December of 2016 and April of 2017." *Id.* at 2.

Petitioner's affidavit also described the many physical symptoms she purportedly experienced in the course of her illness, including a tingling sensation in her tongue, throat, face, and spine, as well as muscle aches, weakness, and other pain. Pet. Aff. at 2. And Ms. Welch described in detail the many ways her illness affected her life. In particular, she recounted that she was too weak to pick up her grandson, that her pain caused her to wake up frequently during the night, that she struggled with basic motor functions such as walking and buttoning clothes, and

that her pain made it difficult for her to perform many elements of her work in a café, such as typing, writing, handling money, and preparing food. *Id.* at 2–4.

III. Expert Reports

Petitioner filed two expert reports, both from her treating neurologist, Dr. Schoen. *See generally* Ex. 8, filed Oct. 25, 2018 (ECF No. 11-1) ("Schoen First Rep."); Ex. 10, filed Feb. 28, 2019 (ECF No. 15-2) ("Schoen Second Rep."). Respondent did not file an expert report in this case.

In his first report, Dr. Schoen provided a detailed history of his visits with Petitioner, which (as noted above) began in March 2017. Schoen First Rep. at 1–2. He recounted her symptoms and test results in a manner consistent with what is reflected in the records for those visits. *See id.* He recalled that, at his last visit with Petitioner on August 7, 2017, "her symptoms had resolved," although she was still experiencing an aching sensation in her left arm and left ankle. *Id.* at 2. Also consistent with the medical records, he noted that, when treating Petitioner, he "felt that she had probable postvaccination neuropathy." *Id.* at 2. Dr. Schoen stated that he considered Petitioner to have a "presumed etiology of postvaccination neuropathy," but that her condition also could have been rheumatological in origin. *Id.* In this first report, Dr. Schoen did not definitively opine that Petitioner's condition was properly considered to be GBS, however, instead maintaining a more general characterization of her constellation of symptoms as a "neuropathy." *See id.* He also did not discuss any possible mechanisms of vaccine causation, nor what would constitute an appropriate timeframe for onset under any such mechanism. *See id.*

Dr. Schoen addressed some of these issues in his second report. On the question of Petitioner's proper diagnosis, Dr. Schoen now noted that Petitioner "did *not* show evidence of typical findings of [GBS]," but that he nevertheless suspected "extremely mild" GBS given her symptoms and the wide range of GBS severity. Schoen Second Rep. at 1–2 (emphasis added). Regarding the timing of onset, he stated that GBS is most commonly caused by gastrointestinal viral illnesses, and that "[s]ymptoms usually begin one to 3 weeks after the inciting illness." *Id.* at 2. In Petitioner's case, he deemed the time of her symptom onset "still unclear," as "[s]ome of my notes indicate that it may have been weeks, some indicate up to a month or so." *Id.*

Dr. Schoen also addressed possible alternative causes of Petitioner's illness, acknowledging that diabetes (from which Ms. Welch suffered) is a common cause of neuropathy. Schoen Second Rep. at 2. However, because Petitioner experienced "acute onset of symptoms with absent reflexes then recovery with return of reflexes," he deemed her course inconsistent with diabetes-caused neuropathy. *Id.* For the same reason, he wrote that her frequent UTIs were also likely not the cause of her condition. *Id.* He provided no further explanation or medical literature to explain why the symptomology and recovery would be different in diabetes- or UTI-caused neuropathy, as distinguished from a vaccine-caused condition.

In light of the unclear timing of Petitioner's symptom onset and the existence of possible alternative causes for her condition, Dr. Schoen concluded his second expert report with a statement facially damaging to Petitioner's case: that he "CAN NOT state within a reasonable degree of medical certainty that the flu vaccine was the competent producing cause of her very mild symptoms." Schoen Second Rep. at 2 (emphasis in original).

IV. Procedural History

As noted above, Ms. Welch filed her Petition on April 4, 2018. Respondent filed his Rule 4(c) Report on November 29, 2018. ECF No. 12. Petitioner's medical records were submitted over the course of many months, the last of which were filed in February 2019. Dr. Schoen's two reports were filed in October 2018 and February 2019. As noted above (and after my review of Dr. Schoen's second report), I suggested to Petitioner in March that she consider dismissal of this claim, but she instead decided to seek a ruling on the record despite my informed misgivings. *See* Order (non-PDF), dated Mar. 26, 2019. The parties submitted their respective briefs in the spring of 2019, and this case is now ripe for decision.

V. Parties' Respective Arguments

A. *Petitioner's Memorandum*

Petitioner asserts that she has made a satisfactory showing under *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005), and is thus entitled to an award of compensation. However, she does not clearly identify what injury she alleges was caused by the flu vaccine. While her Petition identified her injury as GBS (Pet. at 1), she now shifts to a more general claim of a nonspecific neurologic injury in her memorandum. *See, e.g.*, Mot. at 9, 11.

Ms. Welch argues that her injury could have been vaccine-caused. Although she does not lay out a specific mechanism by which the flu vaccine could cause the type of nonspecific neurological injury she alleges, Ms. Welch highlights Dr. Schoen's statement in the medical record that Petitioner's condition could be a possible post-vaccination neuropathy, including possible mild GBS, as well as his opinion in his first report stating that Petitioner's condition may have been a post-vaccination neuropathy. Mot. at 8 (citing Ex. 5 at 15; Schoen First Rep. at 2). She also asserts that no other condition in her medical record can properly be considered the cause of her neuropathy, citing Dr. Schoen's statement that the absence and subsequent return of reflexes Petitioner experienced in the course of her illness would not be expected in a case of diabetes- or UTI-caused neuropathy. *Id.* (citing Schoen Second Rep. at 2). As further support for the persuasive value of Dr. Schoen's opinion, as well as the possibility of vaccine-caused non-specific neurological injury, Petitioner draws on *Thompson v. Secretary of Health & Human Services*, No. 12-475V, 2017 WL 4875898 (Fed. Cl. Spec. Mstr. Oct. 4, 2017), in which the special master

found that a reputable causation theory existed for a vaccine-caused non-specific neurologic injury based on the opinion of a treating neurologist. *Id.* at 9.

In addition to statements by Dr. Schoen, Petitioner cites additional evidence to support her contention that the flu vaccine could have caused her injury. She notes that the Vaccine Injury Table includes a claim of GBS following the flu vaccination, which "demonstrates that the Program accepts that an influenza vaccination can cause Guillain-Barré syndrome." Mot. at 9. Ms. Welch also points out that she experienced no neurologic symptoms before receiving the flu vaccine on October 18, 2016. *Id.* at 8.

On the question of whether the flu vaccine actually did cause Petitioner's injury, she again cites to Dr. Schoen's statements on the possibility of vaccine causation. Mot. at 9 (citing Ex. 5 at 15). She also reiterates that Dr. Schoen refuted other possible causes of her injury. *Id.* She does not, however, explain how the portions of his opinion that she relies upon square with his subsequent statement, in which he expressly *declines* to opine that the flu vaccine caused her illness.

Finally, Petitioner asserts that her injury began in a medically-reasonable timeframe after vaccination, although she does not clearly identify when her illness began, nor what a reasonable timeframe would be. Mot. at 9–10. She notes, however, that she repeatedly informed treating physicians that her symptoms began after she received the flu vaccine. *Id.* If symptoms began in December 2016, as many records reflect, Petitioner asserts that this is a medically reasonable timeframe, as the Vaccine Injury Table lists a maximum onset period of forty-two days after vaccination, which in Petitioner's case would be November 29, 2016; thus, she concludes that a December onset is "logically within the time frame." *Id.* at 10. She argues in the alternative that her symptoms may have begun even earlier than December 2016, given that some records state that they began as soon as two to four weeks after vaccination. *Id.* (citing Ex. 5 at 10, 13).

B. *Respondent's Opposition*

Respondent asserts that Petitioner has not satisfied her evidentiary burden and that her claim must therefore be dismissed. As a threshold matter, Respondent notes that Petitioner bears the burden of proving that she actually suffered the injury she alleges, but that Petitioner's medical records do not support a diagnosis of GBS, as she had gradual symptom onset, a normal lumbar puncture and electrodiagnostic test results, and an absence of documented weakness. Opp. at 7 (citing 42 C.F.R. § 100.3(c)(15)).

Turning to the *Althen* prongs, Respondent argues that Petitioner has failed to satisfy all three. Neither Dr. Schoen nor any other expert has set forth a theory explaining how the flu vaccine could cause Petitioner's injury, Respondent asserts. Opp. at 8. Dr. Schoen's second report effectively retracted his initial statement about the possibility of vaccine causation, since he was

unable to say to a reasonable degree of medical certainty that Petitioner's injury was likely vaccine caused. *Id.* (citing Schoen Second Rep. at 2). Respondent maintains that Petitioner's reliance on *Thompson* is unjustified, because in that case (unlike here), the treating neurologist who served as an expert actually offered a medical theory explaining how a vaccine could cause the injury at issue. *Id.*

Respondent also asserts that Petitioner's reliance on the Vaccine Injury Table timeframe for GBS onset following flu vaccination is misplaced. Opp. at 8–9. He notes that Petitioner no longer seems to allege GBS as her injury, making the timeframe listed in the Table irrelevant. *Id.* at 9. He argues further that Petitioner's symptom onset was most likely in December 2016, which was more than forty-two days after vaccination. *Id.* For these reasons, Respondent argues that Petitioner has failed to meet her burden under *Althen*.

C. *Petitioner's Reply*

In a brief reply, Petitioner responds to two points raised by Respondent. First, she asserts that Dr. Schoen's statement that he could not say to a reasonable degree of medical certainty that Petitioner's illness was vaccine-caused does not undermine her showing on *Althen* prong one. Reply at 1–2. Rather, Dr. Schoen's earlier statements, in which he raised the possibility of vaccine causation, are by themselves sufficient to satisfy the Vaccine Program's lenient preponderance standard. *Id.* In support, Petitioner discusses *Moberly v. Secretary of Health & Human Services*, 592 F.3d 1315 (Fed. Cir. 2010), in which the Court of Appeals for the Federal Circuit affirmed a denial of compensation. *Id.* at 2. While several treating physicians in that case had recorded the temporal association between the petitioner's vaccination and subsequent injury, none expressly opined that the vaccination likely *caused* the injury. *Id.* (discussing *Moberly*, 592 F.3d at 1323). On appeal, the Federal Circuit panel stated that, had any treaters offered such an opinion, "it could have been probative with respect to causation." *Moberly*, 592 F.3d at 1323. Because Dr. Schoen provided such an opinion in this case, Petitioner asserts, she has made a sufficient showing on the question of vaccine causation. Reply at 2–3.

Petitioner also returns to the question of whether her illness developed within a medically-reasonable time period after vaccination. Reply at 3. She points to statements from Dr. Schoen in her medical record memorializing that her illness developed after she received the flu vaccine, as well as her own statements to treaters of the same, as support for her contention that she has satisfied *Althen*'s third prong. *Id.*

VI. Applicable Legal Standards

A. *Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—

corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 11(c)(1), 13(a)(1)(A), 14(a); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[3] Furthermore, a petitioner must show that he has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." Section 11(c)(1)(D).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(a)(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation."

[3] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States*, 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first Althen prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)); *see also Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g.*, *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury]") (emphasis added). Regardless, petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" an injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without op.*, 475 F. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also align with the theory of how the relevant vaccine can cause the injury in question. *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the

record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub. nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight")).

In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Reports*

Establishing a sound and reliable medical theory often requires a petitioner to present statements from medical experts in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has been employed to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert reports, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert

testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Determination to Resolve Case Without Hearing*

I have opted (without objection by either side) to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports, rather than after a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers when, in the exercise of their discretion, they conclude that such a means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x 809, 812 (Fed. Cir. 2018); *Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided matters on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

A. *Petitioner Could Not Establish a Table Claim*

At the outset, although Petitioner has not expressly pursued a Table claim, she references the Table in support of her claim (primarily based upon the fact that her onset occurred right around the end of the forty-two-day timeframe for a flu vaccine-GBS claim). I will therefore briefly address why she could not meet the requirements for one even had she so attempted. As noted above, the Vaccine Injury Table includes GBS following flu vaccination with onset between three and forty-two days after vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). Petitioner received the flu vaccine on October 18, 2016, making the forty-second day after vaccination November 29, 2016. However, Petitioner clearly cannot establish she experienced GBS (as defined by the Table) within that timeframe. *See id.* at § 100.3(c)(15)(i) (describing GBS as an acute, monophasic condition, with a nadir of weakness no more than twenty-eight days after initial onset, followed by a clinical plateau); *Taylor v. Sec'y of Health & Human Servs.*, No. 90-857V, 1991 WL 115031, at *3 (Cl. Ct. Spec. Mstr. June 12, 1991) ("[t]he Table provides a presumption of causation only where a Table injury first manifests itself during the Table period").

First, the records at best support the conclusion that Petitioner began to experience neurologic symptoms no sooner than December 2016—but that those symptoms then meandered

over time for many months. They never became acute in the manner that GBS is understood medically to progress. GBS is thought to be an acutely-presenting neuropathic injury involving the peripheral nerves that progresses to nadir within two to four weeks in most cases, thereafter resolving (albeit with sequelae that can vary in severity). *See, e.g.*, *Chinea v. Sec'y of Health & Human Servs.*, No. 15-95V, 2019 WL 1873322, at *28–29 (Fed. Cl. Spec. Mstr. Mar. 15, 2019), mot. for review filed Apr. 17, 2019; *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *21 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). Petitioner was, in fact, never definitively diagnosed with GBS—even by Dr. Schoen. And although her waxing and waning mild symptoms could arguably be understood as chronic immune demyelinating polyradiculopathy ("CIDP"),[4] that diagnosis is an excluding factor to establish a Table claim of GBS. 42 C.F.R. § 100.3(c)(15)(vi).

Second, Petitioner's overall course does not fit the Table timeframe, even if she can establish that the first neurologic symptom began at the end of the defined period. Petitioner did not report any symptoms to a medical provider until February 21, 2017—more than four months after vaccination—and the records closest in time to her purported symptom onset reflect that her symptoms began in December 2016. *See, e.g.*, Ex. 5 at 1 (informing Dr. Schoen on March 9, 2017, that her symptoms began in December 2016). Her subsequent statements asserting that the symptoms began two to four weeks after vaccination have less persuasive value than her first reports to treaters, particularly when she admitted that she was unable to recall the date of her vaccination (thus making her attempts to link her symptom onset to vaccination even more speculative). *See Burns*, 3 F.3d at 417 (contemporaneously-created medical records may be given more weight than later-in-time statements to the contrary). Based on the available records, the most likely time of Petitioner's symptom onset appears to be no earlier than some unspecified date in December 2016—more than forty-two days after vaccination. Therefore, even if Petitioner's injury could properly be characterized as GBS, she does not satisfy the timeframe for onset set forth in the Table, and a Table claim therefore could not succeed.

B. *Petitioner Did Not Likely Have GBS*

Even if Petitioner is not held to the strict Table requirements, she cannot otherwise demonstrate that her neurologic injuries constitute GBS as it is medically understood. There is no question that she did not formally receive a GBS diagnosis. Although at one point her primary neurologic treater, Dr. Schoen, included GBS in her differential, it appears he ultimately concluded she at most had experienced some kind of mild neuropathy. *See* Schoen Second Rep. at 2; Ex. 5 at 15. In addition, the symptoms Petitioner alleges to have experienced are not consistent with what has been deemed GBS in prior Program cases, as noted above.

[4] CIDP is a slow, progressive autoimmune condition characterized by progressive weakness in the limbs, tingling or numbness in the fingers and toes, and fatigue. *Dorland's Illustrated Medical Dictionary* 1491 (32nd ed. 2012).

Indeed, the record reveals that more than six weeks passed from Petitioner's vaccination before she alleges to have experienced even initial symptoms. *See* Ex. 4 at 3; Ex. 5 at 1. Thereafter, she did not feel the need to seek medical intervention until February 21, 2017, more than four months post-vaccination. Ex. 4 at 3. This history does not describe GBS's course—even in individuals who are later properly diagnosed with it. *See, e.g., Chinea*, 2019 WL 1873322, at *30–32 (noting that petitioner experienced ongoing fatigue and malaise for several months before developing GBS, but finding that her earlier symptoms could not be attributed to subsequently-diagnosed GBS). And although Ms. Welch did complain of symptoms that appear consistent with those GBS patients often suffer, such as areflexia and paresthesia, medical testing did not confirm GBS either. Ex. 5 at 5. At best, then, Petitioner's claim depends on a finding that the flu vaccine could cause a mild neuropathy.

C. *Petitioner Cannot Meet her Burden to Establish a Causation-in-Fact Claim*

Petitioner has not demonstrated that even a claim of a mild post-vaccination neuropathy could satisfy the *Althen* prongs. The largest and most obvious weakness to her claim is her expert's effective recanting of his opinion, as evidenced in the conclusion of his second report. *See* Schoen Second Rep. at 2. Program experts are typically asked by counsel to offer an opinion "to a reasonable degree of medical certainty," based on the Program's preponderance standard of proof. *See, e.g., Lampe*, 219 F.3d at 1367. Here, Petitioner's own expert—and treater, no less—has indicated he *cannot* do so in light of his overall review of the record and consideration of Petitioner's history. Even in a case in which an expert offers a more consistent opinion, a petitioner cannot credibly pick and choose only those portions of his opinion that support her claim, while ignoring the impact of those portions that openly undermine it; at best, she can argue for giving more weight to certain aspects of an opinion over others (although Petitioner offers no explanation whatsoever for why I should do so here). In effect, Petitioner has "lost" her expert, even if parts of his opinion were helpful to her claim.[5]

Moreover, even if I ignore the above, Dr. Schoen's opinion is not otherwise persuasive. He merely hypothesized that her illness *could* have been vaccine-caused, rather than offering an opinion it likely was, largely relying on his sense that other possible causes were less likely. *See* Schoen Second Rep. at 2. Petitioner also attempts to draw comparisons between this case and *Thompson*, in which a petitioner was awarded compensation for a non-specific neurologic injury based in part on testimony from her treating neurologist, who also served as an expert in the case. But the expert in that case laid out a theory explaining how the relevant vaccine could cause the claimed injury in that case, while Dr. Schoen has not done so here. *See Thompson*, 2017 WL 4875898, at *11 (discussing neurologist's theory that two administrations of different flu vaccines

[5] In many cases in which an expert indicates to a claimant that he cannot offer an opinion on behalf of causation, the petitioner opts to dismiss the case—a course of action I proposed herein but which Ms. Welch refused to accept. *See, e.g., Pleasant v. Sec'y of Health & Human Servs.*, No. 17-610V, 2018 WL 7132251, at *1 (Fed. Cl. Spec. Mstr. Nov. 28, 2018) (petitioner voluntarily dismissing case after failing to secure expert support for vaccine causation).

caused petitioner's neurologic injury by means of an anamnestic response). The fact that petitioners have succeeded with other claims alleging a vague neuropathic injury does not mean that *this* claim should succeed, given the fact that Petitioner's existing expert was unable to offer the opinion that the flu vaccine was the most likely cause for her injury.

Second, Petitioner has failed to demonstrate that the flu vaccine actually did cause her neurologic injury. While she asserts that she was free of neurologic symptoms prior to vaccination, a temporal association between vaccination and subsequent symptom onset does not suffice to prove causation. *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1337, 1341 (Fed. Cir. 2014); *Moberly*, 592 F.3d at 1323. And although treating physicians' statements attributing causation to a vaccine are unquestionably entitled to some probative value, I cannot give great weight to Dr. Schoen's medical record statements in this case. The statements Petitioner highlights—that she "likely had postvaccination neuropathy" and that her symptoms were "most likely consistent with a post viral/possible vaccination neuropathy"—appear to reflect Dr. Schoen's analysis after hearing Petitioner's self-reported history, in which she informed him that her symptoms began two to four weeks after vaccination. Ex. 5 at 15; Schoen First Rep. at 2. Such assertions are belied by records closer in time to symptom onset, which show that her symptoms likely began more than six weeks after vaccination. *See, e.g.*, Ex. 5 at 1 (reporting at first visit with Dr. Schoen in March 2017 that symptoms began in December 2016); *see also* Pet. Aff. at 2 (Petitioner placing symptom onset in December 2016 in sworn affidavit). Expert opinions based on erroneous factual assumptions are of little probative value, and I therefore cannot give substantial weight to these. See *Dobrydnev v. Sec'y of Health & Human Servs.*, 556 F. App'x 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")).

I am also unpersuaded by Petitioner's assertion that she has satisfied *Althen* prong two by eliminating alternative causes of her neuropathy. It is well-established in the Vaccine Program that merely eliminating possible alternative causes does not establish causation. *Thomas v. Sec'y of Health & Human Servs.*, No. 01-645V, 2007 WL 470410, at *25 (Fed. Cl. Spec. Mstr. Jan. 23, 2007). Furthermore, Petitioner relies on Dr. Schoen's second expert report in support for her elimination of her diabetes and recurrent UTIs as possible causes of her illness, but given the lack of medical literature support or further explanation in Dr. Schoen's bald assertion that the return of reflexes would not be seen in a diabetes- or UTI-caused neuropathy, I cannot give this statement anything more than minimal weight.

Finally, Petitioner has failed to show that her neuropathy developed within a medically-reasonable timeframe after vaccination. She has offered *no* evidence showing what would constitute a medically-reasonable timeframe for a non-specific neurological injury following

receipt of the flu vaccine, or that a six-week timeframe is medically reasonable for a nonspecific neurologic injury that subsequently waxes and wanes for several months. Her statements to treaters that she developed neuropathy symptoms after vaccination merely reflect the fact that her symptoms *post-dated* vaccination—they do not provide medical or scientific evidence that such symptoms would reasonably occur in this timeframe—or that they would progress over several months time.

CONCLUSION

Having reviewed the medical records, expert reports, and arguments put forth by the parties, I do not find that Petitioner has established with sufficient preponderant evidence that the flu vaccine she received on October 18, 2016, caused her subsequent neuropathy (regardless of whether it can properly be characterized as GBS). Accordingly, she has not established entitlement to a damages award and I must **DISMISS** her claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.[6]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master

[6] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.